



PATENT  
Docket No. 2026-4298US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Zuzana KOSSACZKA et al.      Group Art Unit: 1645  
Serial No : 09/653,433      Examiner: Virginia Allen Portner  
Filed : September 1, 2000  
For : **A METHOD OF IMMUNIZING HUMANS AGAINST  
SALMONELLA TYPHI USING A Vi-rEPA CONJUGATE  
VACCINE**

**DECLARATION OF  
ZUZANA KOSSACZKA, SHOUSUN CHEN SZU, JOHN B. ROBBINS,  
RACHEL SCHNEERSON AND JOSEPH SHILOACH  
CONCERNING CO-AUTHORSHIP**

COMMISSIONER FOR PATENTS  
Washington, D.C. 20231

Sir:

We, Zuzana Kossaczka, Shousun Chen Szu, John B. Robbins, Rachel Schneerson and Joseph Shiloach, declare as follows:

1. We are the co-inventors of the above-referenced patent application.
2. Drs. Zuzana Kossaczka, Shousun Chen Szu, John B. Robbins, Rachel Schneerson and Joseph Shiloach are co-authors of an abstract Szu et al., "Phase II trials of conjugates of *S. Typhi* Vi and of *S. Paratyphi A* O-Specific Polysaccharide (O-SP) Conjugates in Dong Thap Province, Vietnam," Abstract S7-1 form the Abstract Book of the "Third Asia-Pacific Symposium on Typhoid Fever and Other Salmonellosis", hosted by the Indonesian Society for Microbiology, Denpasar, Bali-Indonesia, December 8-10, 1997 ("Szu et al. (1997)).
3. Co-inventor Dr. Rachel Schneerson is Research Medical Officer in the Laboratory of Developmental & Molecular Immunity, National Institute of Child Health &

Human Development, National Institutes of Health, Bethesda, Maryland. Dr. Schneerson is named as a co-inventor because she participated in every aspect of the study from the initial discussions of how to form a conjugate vaccine with this unusual polysaccharide, Vi, with the decision to use rEPA as the carrier. In addition, Dr. Schneerson's clinical experience in vaccine trials were invaluable in designing the clinical study, writing the protocols for every component of the clinical study, developing the ELISA for assay of human serum antibodies and finally in participating in the vaccination and monitoring at the site.

4. Co-author Edward Konadu was a visiting fellow in the Laboratory of Developmental & Molecular Immunity, National Institute of Child Health & Human Development, National Institutes of Health, Bethesda, Maryland, working under Dr. Szu's supervision and control on the experiments described in the publication.

5. Co-author A. Karpas, D.A. Bryla and F.-Y.C. Lin are collaborators in setting-up the study at the National Institutes of Health, Bethesda, Maryland, USA. They were not inventors of the subject matter of this patent application. They were listed as co-authors of the article in order to receive credit for having collaborated in the research program.

6. Co-author D.D. Trach, is principle investigator at the National Institute of Hygiene and Epidemiology in Vietnam. Co-authors H.B. Khiem and N.T.T. Thuy are associate investigators at the Pasteur Institute of Ho Chi Minh City, Vietnam. Co-author V.A. Ho is associate investigator at the Huu Nghi Hospital, Vietnam. They were not inventors of the subject matter of this patent application. They were listed as co-authors of the article in order to receive credit for having collaborated in the research program.

7. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

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Date

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Zuzana Kossaczka

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Date

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Shousun Chen Szu

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Date

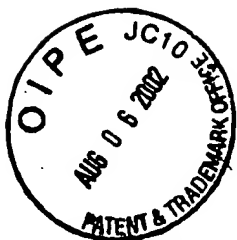
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John B. Robbins

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Date

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Rachel Schneerson

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Joseph Shiloach  
Joseph Shiloach



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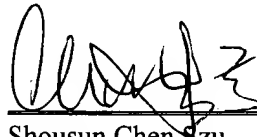
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Zuzana Kossaczka



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Shousun Chen Szu



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John B. Robbins



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Rachel Schneerson

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July 25, 2002  
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E. Kossaczka  
Zuzana Kossaczka

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Shousun Chen Szu

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John B. Robbins

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Rachel Schneerson

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Joseph Shiloach